ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

At the outset, Applicants must request again that the finality of the last Office Action be withdrawn. The Office Action contains *a new ground of rejection* over Nelson, U.S. Patent No. 4,446,140, alone. Such new ground of rejection could not have been necessitated by Applicants' previous amendment since that amendment did not amend the claims. Consequently, this rejection should not have been made final, and Applicants respectfully request that the Examiner withdraw the finality of the last Office Action.

In the event that the finality of the Office Action is not withdrawn, then Applicants respectfully request that the Examiner enter and consider the amendments above. The Office Action should not have been made final since the rejection based on Nelson alone is a new ground of rejection. If the finality of the Office Action is maintained for whatever reason, fundamental notions of fairness alone dictate that Applicants have the right to have their response entered and considered.

Applicants thank Examiner George for his indication that claims 10 and 11 were allowable in substance. Claim 10 has been made independent and a new method claim 14 is added which is dependent on claim 10 or 11. Therefore, Applicants seek an early notice that claims 10, 11 and 14 have been allowed.

Claim 12 has been amended to reflect a change in dependency.

A clean copy of claims 10 and 12 appears above. A mark-up showing the changes that have been made to this claim using brackets and underlining is attached.

A new preparation claim 13 is added and also a new method claim 15, which is dependent on new claim 13. Claim 13 has the scope recently allowed in the corresponding European application. Since the European concepts of lack of novelty and lack of inventive step are similar to our concepts of anticipation and obviousness, respectively, the fact that this claim has been allowed in Europe over the prior art can be taken into consideration by the Examiner in his consideration of the allowability of claim 13. For that reason, Applicants respectfully request that the Examiner give special consideration to claims 13 and 15.

Applicants do not believe that any of the amendments introduces any new matter. Support for the limitation in new claim 13 that "element A is released from the preparation before element B" can be gleaned, for example, from the specification at page 3, line 26, wherein it is taught that "the local anaesthetic is released first."

The sole substantive issue is the rejection of claims 1-9 and 12 under 35 USC § 103(a) as being obvious over Nelson, U.S. Patent No. 4,446,140, alone. In response, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

First, although the Examiner takes the position that Nelson mentions combinations of dextromethorphan and analgesics or anesthetics, Nelson does not disclose the tablet structure required by claim 9. Claim 9 expressly requires "a inner core tablet coated with an outer coating." There is no teaching or suggestion of such a tablet structure in Nelson, and Applicants submit that it is possible to have a tablet containing multiple active ingredients that are *not* in the arrangement required by claim 9. Accordingly, claim 9 should not have been rejected, and Applicants respectfully request that the Examiner reconsider and withdraw the rejection as to claim 9.

Second, a similar argument can be made with respect to claim 13. Nelson does not teach or suggest that "the preparation is formulated such that element A is released from the preparation before element B upon oral administration." Accordingly, claim 13 should not be subject to this rejection, and Applicants respectfully request that the Examiner indicate the allowability of claim 13.

Third, the Examiner has nowhere dealt with the specific limitations of claims 2, 3 or 6-8. Applicants would remind the Examiner that according to *Manual of Patent Examining Procedure* ("MPEP") § 2143:

> "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest *all the claim limitations*. [Emphasis added.]"

Consequently, this rejection is improperly applied as to claims 2, 3 and 6-8 unless the Examiner can show where in Nelson the limitations of these claims are taught or suggested. Since the Examiner has not yet done this, Applicants submit that the Examiner has not made out a *prima facie* case of obviousness as to these claims. Therefore, Applicants also respectfully request that the Examiner indicate the allowability of claims 2, 3 and 6-8.

Finally, Applicants take issue with the Examiner's position with respect to dextromethorphan. That dextromethorphan is "essentially free of analgesic * * * properties" means that persons skilled in the art would not use it to treat pain. Whether other analgesics present in a preparation containing dextromethorphan could enhance the properties of the dextromethorphan and thus increase its analgesic properties is a purely speculative exercise and

not a proper basis for obviousness. There is no express teaching of such enhancement in Nelson. To the extent the Examiner considers inherency a possibility, then Applicants would remind the Examiner that, as pointed out by the Board of Patent Appeals and Interferences in *Ex parte Levy*, 17 USPQ2d 1461, 1463-1464 (BPAI 1990):

> "[T]he initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention rests upon the Examiner. * * * In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art. [Emphasis in original.]"

Applicants submit that the Examiner has not discharged this initial burden. The Examiner has only raised a mere possibility. It is certainly not the case that any other analgesics in Nelson's preparations *necessarily* enhance the analgesic properties of dextromethorphan. As pointed out in *In re Robertson*, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999), inherency is not established by probabilities or possibilities, and the mere fact that a property may result from a given circumstances is not sufficient; instead it must be shown that such property *necessarily* inheres in the thing described in the reference. Certainly, this cannot be shown with respect to Nelson. Therefore, Applicants respectfully request that the Examiner indicate that all claims are allowable.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (914) 332-1700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,

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By

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.116 and the attached Mark-Up Showing the Changes Made in the Previous Claim to Yield the Claim as Amended Above (11 pages total) are being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: November 27, 2002

By

Kurt G. Briscoe

MARK-UP SHOWING THE CHANGES MADE IN THE PREVIOUS CLAIM TO YIELD THE CLAIM AS AMENDED ABOVE

--10. (Once Amended) [The preparation according to claim 9,] **A preparation** which **can be administered orally and** is in the form of a inner core tablet coated with an outer coating, wherein the outer coating comprises at least one locally acting analgesic with a rapid onset of action (element A) selected from the group consisting of benzocaine, amethocaine, amylocaine, butacaine, butoxycaine, butyl aminobenzoate, chloroprocaine, chlormecaine, cyclomethycaine, isobutamben, meprylcaine, oxybuprocaine, procaine, propipocaine, proxymetacine, tricaine, lidocaine, bupivacaine, butanilicaine, carticaine, cinchocaine, clibucaine, etidocaine, mepivacaine, oxethazaine, prilocaine, ropivacaine, ethyl p-piperidinoacetyl-aminobenzoate, tolycaine, trimecaine and vadocaine, and the inner core tablet comprises at least one systemically acting analgesic with a sustained action (element B) selected from the group consisting of aceclofenac, alclofenac, bromofenac, diclofenac, fenclofenac, acemetacin, amfenac sodium, bendazac, glucametacin, oxametacin, acetanilide, alminoprofen, ibuprofen, ketoprofen, flurbiprofen, naproxen, oxaprozin, acetyl salicylic acid, salts of acetylsalicylic acid, diflunisal, etersalate, fosfosal, salol, salsalate, salacetamide, amidopyrine, dipyrone, droxicam, isoxicam, piroxicam, azapropazone, bumadizone calcium, oxyphenbutazone, etodolac, galfenine, sodium meclofenamate, mefenamic acid, morniflumate, indomethacin, paracetamol, paracetamol derivatives, anirolac, benzpiperylone, benzydamine hydrochloride, sodium butibufen, chlorthenoxazine, cinmetacin, clonixin, cloracetadol,

difenpiramide, diproqualone, etenzamide, famprofazone, flupirtine maleate, ibuproxam, indoprofen, isamfazone, meloxicam, metiazinic acid, metifenazone, nifenazone, niflumic acid, mimesulide, pirazolac, pranoprofen, proquazone, protizinic acid and ramifenazone.--

--12. (Once Amended) A method of alleviating pain in a patient in need thereof comprising administering to said patient a preparation according to any one of claims 1-[11]9.--